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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/714,085 | 11/14/2003 | Samuel Zalipsky | 55325-8167.US06 | 9528 |

22918 7590 03/16/2007
PERKINS COIE LLP
P.O. BOX 2168
MENLO PARK, CA 94026

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| EXAMINER |
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KISHORE, GOLLAMUDI S

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| ART UNIT | PAPER NUMBER |
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1615

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 03/16/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/714,085

Applicant(s)

ZALIPSKY ET AL.

Examiner

Gollamudi S. Kishore, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>See Continuation Sheet</u> | 6) <input type="checkbox"/> Other: ____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :4-30-04;6-14-04;10-3-05;8-2-06;11-3-06;12-22-06.

DETAILED ACTION

Claims included in the prosecution are 1-10.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-42 of U.S. Patent No. 6,365,179 in view of Rahman (5,648,090), Rahman (5,560,923), Thierry (FASEB J, 1993), Warren et al (Cancer Research, 1992) individually or in combination.

The claims in the said patent are drawn to the same liposomes containing mitomycin C and method of retaining mitomycin C. What is lacking is a method of administering mitomycin C to a multi-drug resistant cell or reducing the cytotoxicity as in instant claims.

The references of Rahman (090), (923), Thierry, and Warren et al each teach the ability of liposomes to overcome the multi-resistance of cells to anti-cancer agent when they are encapsulated within the liposomes (Figures and columns 6-8 in 090; Example 4 in 923; abstracts in Thierry, and Warren et al).

It would have been obvious to one of ordinary skill in the art with a reasonable expectation of success to use the liposomal compositions in 6,365,179 to treat multi-drug cells since the references of Rahman, Thierry, and Warren et al each teach that liposomes have the ability to overcome the multi-drug resistance to anti-cancer drugs. Reduction of the cytotoxicity of mitomycin C would have been obvious to one of ordinary skill in the art since liposomes are known to reduce the toxicity of anti-cancer agents as also evident from Rahman 090.

3. Claims 1-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,984,396 in view of Rahman (5,648,090), Rahman (5,560,923), Thierry (FASEB J, 1993), Warren et al (Cancer Research, 1992) individually or in combination.

The claims in the said patent are drawn to the same liposomes containing mitomycin C. What is lacking is a method of administering mitomycin C to a multi-drug resistant cell or reducing the cytotoxicity as in instant claims.

The references of Rahman (090), (923), Thierry, and Warren et al each teach the ability of liposomes to overcome the multi-resistance of cells to anti-cancer agent when they are encapsulated within the liposomes (Figures and columns 6-8 in 090; Example 4 in 923; abstracts in Thierry, and Warren et al).

It would have been obvious to one of ordinary skill in the art with a reasonable expectation of success to use the liposomal compositions in 6,984,396 to treat multi-drug cells since the references of Rahman, Thierry, and Warren et al each teach that liposomes have the ability to overcome the multi-drug resistance to anti-cancer drugs. Reduction of the cytotoxicity of mitomycin C would have been obvious to one of ordinary skill in the art since liposomes are known to reduce the toxicity of anti-cancer agents as also evident from Rahman 090.

4. Claims 1-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10, 11 and 22-47 of U.S. Patent No. 6,342,244 in view of Rahman (5,648,090), Rahman (5,560,923), Thierry (FASEB J, 1993), Warren et al (Cancer Research, 1992) individually or in combination.

The claims in the said patent are drawn to the same liposomes containing a therapeutic agent and method of improving blood circulation time. Claims do not specifically recite mitomycin or a method of administering mitomycin C to a multi-drug resistant cell or reducing the cytotoxicity as in instant claims. It would have been obvious to one of ordinary skill in the art to encapsulate any drug including mitomycin C with a reasonable expectation of success.

The references of Rahman (090), (923), Thierry, and Warren et al each teach the ability of liposomes to overcome the multi-resistance of cells to anti-cancer agent when they are encapsulated within the liposomes (Figures and columns 6-8 in 090; Example 4 in 923; abstracts in Thierry, and Warren et al).

It would have been obvious to one of ordinary skill in the art with a reasonable expectation of success to use the liposomal compositions in 6,365,179 to treat multi-drug cells since the references of Rahman, Thierry, and Warren et al each teach that liposomes have the ability to overcome the multi-drug resistance to anti-cancer drugs. Reduction of the cytotoxicity of mitomycin C would have been obvious to one of ordinary skill in the art since liposomes are known to reduce the toxicity of anti-cancer agents as also evident from Rahman 090.

5. Claims 1-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10, 11, 22-47 of U.S. Patent No. 6,849,270 in view of Rahman (5,648,090), Rahman (5,560,923), Thierry (FASEB J, 1993), Warren et al (Cancer Research, 1992) individually or in combination.

The claims in the said patent are drawn to the same liposomes containing a therapeutic agent and method of improving blood circulation time. Claims do not specifically recite mitomycin or a method of administering mitomycin C to a multi-drug resistant cell or reducing the cytotoxicity as in instant claims. It would have been obvious to one of ordinary skill in the art to encapsulate any drug including mitomycin C with a reasonable expectation of success.

The references of Rahman (090), (923), Thierry, and Warren et al each teach the ability of liposomes to overcome the multi-resistance of cells to anti-cancer agent when they are encapsulated within the liposomes (Figures and columns 6-8 in 090; Example 4 in 923; abstracts in Thierry, and Warren et al).

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It would have been obvious to one of ordinary skill in the art with a reasonable expectation of success to use the liposomal compositions in 6,365,179 to treat multi-drug cells since the references of Rahman, Thierry, and Warren et al each teach that liposomes have the ability to overcome the multi-drug resistance to anti-cancer drugs. Reduction of the cytotoxicity of mitomycin C would have been obvious to one of ordinary skill in the art since liposomes are known to reduce the toxicity of anti-cancer agents as also evident from Rahman 090.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK